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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/559,952	ROCHE ET AL.	
	Examiner	Art Unit	
	Padma V. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,7-17,21-25,27-39 and 41-65* is/are pending in the application.

4a) Of the above claim(s) *17,30-39,41-58 and 63-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,7-16,21-25,27-29 and 59-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/27/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response

1. Applicant's election of elected Group I , claims 1, 3-4, 7-17, 21-24, 61 (antibody), 25 (pharmaceutical composition), 59, 60 (kit), and 27-29 and 62 (method) drawn to SEQ ID NO:36 in the reply filed on 12/17/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status of Claims

2. Claims 2, 5-6, 18-20, 26 and 40 are canceled (12/9/05) .

Claims 1, 3-4, 7-17, 21-25, 27-39 and 41-65 are pending.

Claims 1, 3-4, 7-16, 21-24, 25, 27-29 , 59, 60 , 61 and 62 are under examination with respect to elected SEQ.ID.NO:36. Claim 17 is withdrawn from this group as it is drawn to non-elected SEQ.ID.NO:41. Applicant is advised to amend the claims to recite only the elected invention i.e. SEQ.ID.NO:36.

Claims 17, 30-39, 41-58, and 63-65 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 12/17/08.

Specification/ Sequence Requirements

3. This application contains sequence disclosures at page 18 , line 26 (see substitute specification submitted on 12/9/05) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a((1) and (a)(2). However, the fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below: Nucleic acid sequences of 10 or more nucleotides and amino acid sequences of 4 or more residues need to be designated with a sequence identifier. Wherein attention is directed to paragraph(s) §1.82 (c) and (e). Although an examination of this application on the merits can proceed without prior compliance, compliance with the Sequence Rules is required for the response to this Office action to be complete.

Examiner would like to point out that there is no information with regards to SEQ ID NO: of the amino acid sequences present in Figure 1, 18-22 and 26 (table 1) . If the Drawings contain amino acid sequences that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a((1) and (a)(2) then the Brief Description of the Drawings needs to state the SEQ ID NO: for the nucleotide and/or amino acid sequences. Unless the appropriate SEQ ID NO: accompanies the nucleotide and/or amino acid sequences in the actual Drawing sheet.

Full compliance with the sequence rules is required in response to this office action.

Information Disclosure Statement

4. The Information Disclosure Statement submitted on 4/27/06 is reviewed and a signed copy of the same is attached to this Office action.

Claim objection

5. Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 12 depends from claim 1, which is drawn to single antibody that binds to Aspergillus polypeptide SEQ.ID.NO: 36, however claim 12 reads on several antibodies that bind to various homologous peptides of SEQ.ID.NO:36. Therefore, it is an improper dependent form for failing to further limit the subject matter of a previous claim.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 12-16 and the dependent claim 1 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The Written Description Guidelines for examination of patent applications indicates, “the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying

characteristics, i.e., structure or other physical characteristics and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus." (see MPEP 2163).

The claims are drawn to an isolated antibody binding to an extracellular Aspergillus fumigatus polypeptide, isopropylmalate dehydrogenase B , SEQ ID NO: 36, wherein the antibody is further capable of binding a homologous polypeptide, wherein the homologous polypeptide has a sequence identity of at least 39% or 42% or 48% or more, or more 80% or more or 90% or more, to a polypeptide isopropylmalate dehydrogenase B (SEQ ID NO: 36), wherein said homologous polypeptide originates from: an Aspergillus species, such as Aspergillus fumigatus, Aspergillus nidulans, Aspergillus niger, or Aspergillus oryzea, Neurospora crassa, Saccharomyces cerevisiae, a Candida species such as Candida albicans, a Coccidioides species, such as Coccidioides posadasii, or Coccidioides immitis, a Cryptococcus species, such as Cryptococcus neoformans var. neoformans, a Fusarium species, a Pneumocystis species, a Penicillium species, Histoplasma capsulatum" Thus, the scope of the claims includes a genus of "antibodies" and the genus is highly variant, inclusive to numerous structural variants because a significant number of structural differences between genus members is permitted. The specification teaches a single native functioning "isolated antibody that binds to an extracellular Aspergillus fumigatus polypeptide SEQ ID NO:36". The specification does not place any structure, chemical or functional limitations on the variants embraced by "antibody capable of binding a homologous polypeptide, wherein the homologous polypeptide has a sequence identity of at least 39% or 42% or 48% or more, or more 80% or more or 90% or more, to a polypeptide isopropylmalate dehydrogenase B SEQ ID NO: 36 ". The recitation of "antibody capable of binding a homologous polypeptide, wherein the homologous polypeptide has a sequence identity of at least 39% or 42% or 48% or more, or more 80% or more or 90% or more, to a polypeptide isopropylmalate dehydrogenase B SEQ ID NO: 36 " does not convey a common structure or function and is not so defined in the specification. Although the specification teaches that variants can be readily screened, the specification and the claim do not provide any guidance on the structure of the polypeptide and what changes can or can not be made. For example, Lederman et al (Molecular Immunology 28:1171-1181, 1991) disclose that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody (see entire document). Li et al (Proc. Natl. Acad. Sci. USA 77:3211-3214, 1980) disclose that dissociation of immunoreactivity from other activities when constructing analogs (see entire document). "A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when … the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." *In re Curtis*, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004). For inventions in an unpredictable art, adequate written description of a

genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. See, e.g., *Eli Lilly*.

Further, it is not sufficient to define it solely by its principal biological property, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. Per the *Enzo* court's example, (*Enzo Biochem, Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609 (CA FC 2002) at 1616) of a description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) couched "in terms of its function of lessening inflammation of tissues" which, the court stated, "fails to distinguish any steroid from others having the same activity or function" and the expression "an antibiotic penicillin" fails to distinguish a particular penicillin molecule from others possessing the same activity and which therefore, fails to satisfy the written description requirement. Similarly, the function of binding to the claimed antibodies does not distinguish a particular "TR4" polypeptide from others having the same activity or function and as such, fails to satisfy the written-description requirement. Applicant has not disclosed any relevant, identifying characteristics, such as structure or other physical and/or chemical properties, sufficient to show possession of the claimed genus. Mere idea or function is insufficient for written description; isolation and characterization at a minimum are required. A description of what a material does, rather than what it is, usually does not suffice. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

Structural features that could distinguish a ""antibody capable of binding a homologous polypeptide, wherein the homologous polypeptide has a sequence identity of at least 39% or 42% or 48% or more, or more 80% or more or 90% or more, to a polypeptide isopropylmalate dehydrogenase B SEQ ID NO: 36 " in the genus from others in the protein class are missing from the disclosure and the claims. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description, because specific, not general guidance is needed. Since the disclosure does not describe the common attributes or structural characteristics that identify members of the genus, and because the genus is highly variant, the function of the binding of antibody alone is insufficient to describe the genus of ""antibody capable of binding a homologous polypeptide, wherein the homologous polypeptide has a sequence identity of at least 39% or 42% or 48% or more, or more 80% or more or 90% or more, to a polypeptide isopropylmalate dehydrogenase B SEQ ID NO: 36 " of that function equivalently. One of skill in the art would reasonable conclude that the disclosure of a single isolated antibody that binds to an extracellular Aspergillus fumigatus polypeptide SEQ ID NO:36 does not provide a representative number of species of antibodies capable of binding a homologous polypeptide, wherein the homologous polypeptide has a sequence identity of at least 39% or 42% or 48% or more, or more 80% or more or 90% or more, to describe the claimed genus and as a consequence antibodies that bind such. The recitation of "antibody capable of binding a homologous polypeptide, wherein the homologous polypeptide has a sequence identity of at least 39% or 42% or 48%

or more, or more 80% or more or 90% or more " does not convey a common structure nor a common function. As such, generic antibodies that are unrelated via structure and function are highly variant and not conveyed by way of written description by the specification at the time of filing. As such the specification lacks written description for the highly variant genus of single functional antibody and one skilled in the art would not recognize that applicants had possession of the genus of claimed antibodies as instantly claimed.

Therefore, only " an isolated antibody that binds to an extracellular Aspergillus fumigatus isopropylmalate dehydrogenase B polypeptide comprising the amino acid sequence SEQ ID NO: 36,SEQ ID NO:36", but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

8. Claims 25, 27-29 and 62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Claims are drawn to a pharmaceutical composition and a method for the treatment or prevention of fungal infection, comprising administering to an individual a pharmaceutically-effective amount of an isolated antibody binding to an extracellular Aspergillus fumigatus isopropylmalate dehydrogenase B polypeptide comprising the amino acid sequence SEQ ID NO: 36, wherein the fungal infection is an Aspergillus infection, preferably an Aspergillus fumigatus infection, wherein the infection being treated or prevented is selected from the group consisting of: invasive aspergillosis, aspergilloma, allergic aspergillosis, such as allergic bronchopulmonary aspergillosis, wherein the method is combined with other antifungal therapy.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir.1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the relative skill of those in the art, (6) the amount or direction or guidance presented, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary. Although the quantity of experimentation alone is not dispositive in a determination of

whether the required experimentation is undue, this factor does play a central role. For example, a very limited quantity of experimentation may be undue in a fledgling art that is unpredictable where no guidance or working examples are provided in the specification and prior art, whereas the same amount of experimentation may not be undue when viewed in light of some guidance or a working example or the experimentation required is in a predictable established art. Conversely, a large quantity of experimentation would require a correspondingly greater quantum of guidance, predictability and skill in the art to overcome classification as undue experimentation. In Wands, the determination that undue experimentation was not required to make the claimed invention was based primarily on the nature of the art, and the probability that the required experimentation would result in successfully obtaining the claimed invention. (Wands, 8 USPQ2d 1406). Thus, a combination of factors which, when viewed together, would provide an artisan of ordinary skill in the art with an expectation of successfully obtaining the claimed invention with additional experimentation would preclude the classification of that experimentation as undue. A combination of Wands factors, which provide a very low likelihood of successfully obtaining the claimed invention with additional experimentation, however, would render the additional experimentation undue.

1-2 .Breadth of the claims and the nature of the invention.

In regards to the polypeptide of the invention and the breadth of the claims the broadest interpretation that applies is the treatment /prevention of fungal infections selected from invasive aspergillosis, aspergilloma, allergic aspergillosis, such as allergic bronchopulmonary aspergillosis

The nature of the invention is preparing an antibody that binds to an extracellular Aspergillus fumigatus isopropylmalate dehydrogenase B polypeptide comprising the amino acid sequence SEQ ID NO: 36 by injecting purified Aspergillus fumigatus isopropylmalate dehydrogenase B polypeptide , SEQ ID NO: 36 into New Zealand white female rabbits.

While the definition of “pharmaceutical” is broad, it is not so broad to cover any use of a substance on or in the body of a subject, only those uses intended to prevent, diagnose, alleviate, treat, or cure a disease within the animal to which the substance was administered.

In the instant application, the animal to which the claimed composition is administered is merely being used as a bioreactor to make the antibodies that will ultimately be used *in vitro* or in another animal. In addition, the instant specification does not teach how to use the composition, without undue experimentation, for the prevention, , treatment, or cure of a disease in the animal to which the substance is administered.

3-4. The state of prior art and the level of predictability in the art.

In regards to treatment and prevention of fungal infections , enablement is considered to rest on a teaching of in vivo administration of antibody . Feldmesser (Med Mycol. 2005 Nov;43(7):571-87 abstract only as the examiner not able to obtain the full paper copy)teaches that invasive aspergillosis is a disease of immuno compromised hosts and the pathogenesis of this disorder is heavily dependent upon the defect within a given host. Consequently, vaccine development is limited by our understanding of effective host responses and by limitations in our knowledge of fungal molecules that elicit protective immunity.

5. The relative skill in the art.

The relative skill in the art as it relates to the method of the invention is characterized by that of a M.D. or Ph. D. level individual.

6-7. the amount of guidance present and the existence of working examples.
Although the specification discloses the claimed antibody is used to inhibit conidial germination in vitro model , there is insufficient guidance which would enable one skilled in the art to use the claimed antibody for treating and preventing fungal infections.

8. The quantity of experimentation necessary.

The amount of experimentation that is required is undue because making antibodies is routine, it is not routine to use such antibodies in treating and preventing the fungal infections and invasive aspergillosis, aspergilloma, allergic aspergillosis, such as allergic bronchopulmonary aspergillosis and requires more experimentation. Therefore, in view of the overly broad claims, the lack of guidance and working examples provided in the specification, and the high degree of unpredictability as evidenced by the prior art, undue experimentation would be necessary for a skilled artisan to make and use the claimed invention.

It must be noted that the issue in this case is the breath of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. The Applicants make and test position is inconsistent with the decisions of *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it is stated that "... scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient

guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands*, 858 F.2d at 737, 8 USPQZd at 1404 (Fed. Cir. 1988). Therefore, for the instant specification to be enabling, it needs to provide direction/guidance regarding treating and preventing the infections. Absent sufficient guidance/direction one of skill in the art would not be able to practice the claimed invention. Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, the lack of guidance and insufficient working examples provided in the specification and the high degree of unpredictability as evidenced by the state of the prior art, attempting to test antibodies to treat or prevent fungal infections and invasive aspergillosis, aspergilloma, allergic aspergillosis, such as allergic bronchopulmonary aspergillosis encompassed by the claimed invention would constitute undue experimentation. Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention to be considered enabling.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim1, 3, 4, 7-8, 11-16, 21- 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Reijula et al Clinical and Experimental Allergy, vol. 22, No. 5, 1992 , pages 547-543 (IDS4/27/06)

Reijula et al disclose antibodies F6G5, D6E6, B12 (see Table 1) . These antibodies bind to *Aspergillus fumigatus* antigens (see immunoblot of figure 1, lane A, E and F) . Since these antibodies bind to antigens from a mixture of culture filtrate and mycelial extract, it reads on claim 1 because these antibodies bind to antigens obtained from *Aspergillus fumigatus*. The same antibodies read on claims 12-16 and 21-24 as these antibodies bind to various antigens of *Aspergillus fumigatus*. Characteristics such as SEQ.ID.NO:36 are considered the inherent properties of antigens disclosed in figure 1. In the absence of evidence to the contrary the disclosed prior art antibody and the claimed antibody are the same. Since the Office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

As F6G5, D6E6, B12 are monoclonal antibodies and bound to anti-IgG - biotin in an immunoblot (see page 548, right column) it reads on claims 3 and 8 and said antibodies were purified from ascetic

fluids (see page 548, right para, second para) and thus read on claim 11. Antibody F6G5 binds to the cell as shown in Figure 5 and thus read on claim 4. The prior art teaches mice were immunized with culture filtrate and mycelial extract antigens and antibodies were collected (see page 547, right column , last three lines and page 547, lines 1-5) and therefore , it reads on polyclonal antibodies of claim 7.

Antibodies in PBS (i.e., pharmaceutically acceptable carrier, see page 548, right column, lines 8-9) reads on pharmaceutical composition of claim 25. It is acknowledged that weight is given to every term in claim 25 This is why the instant claims drawn to pharmaceutical composition is scrutinized differently from a composition claim under 112, first paragraph. However, under prior art rejections, the term pharmaceutical composition must be weighed with the structural limitations of the claim. If the vaccine pharmaceutical composition merely comprises a known composition, the term carries little weight absent evidence of structural difference. Here, the prior art teaches the same pharmaceutical composition as claimed.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 9-10 and the dependent claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reijula et al Clinical and Experimental Allergy, vol. 22, No. 5, 1992 , pages 547-543 (IDS4/27/06) in view of Queen et al (US Patent 5,530,101, issued 6/25/1996)

Claims 1 and 8 have been disclosed and rejected over Reijula et al as discussed above in paragraph #10. However, the prior art does not teach humanized antibodies and human antibody.

Queen et al teach humanized antibodies and antigen-binding fragments thereof that are less immunogenic in human patients compared to mouse antibodies and thus, better suited for human therapy (see columns 1-3). Therefore all claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention and furthermore the claim would have been obvious because the particular technique of obtained humanized and human antibodies is well known in the art and within the capabilities of one skilled in the art. Also of important note is the fact that a person of ordinary skill in the art has good reason to pursue the known option of making these antibodies which is within his or her technical grasp because this process leads to anticipated success of using for human therapy and therefore it is not the product of innovation but of ordinary skill and common sense.

13. Claims 59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reijula et al Clinical and Experimental Allergy, vol. 22, No. 5, 1992 , pages 547-543 in view of Zuk et al (U.S. Patent No. 4,281,061 issued July 28, 1981) and WO 99/56755

Reijula et al disclose antibodies F6G5, D6E6, B12 (see Table 1) . These antibodies bind to *Aspergillus fumigatus* antigens (see immunoblot of figure 1, lane A, E and F) . Since these antibodies (indicator moiety) bind to *Aspergillus fumigatus* antigens, it reads on claim 59 (a) As F6G5, D6E6, B12 are monoclonal antibodies are diluted in buffer PBS/BSA and bound to antigens in the presence of anti-IgG - biotin in an immunoblot (see page 548, right column) it reads on claim 59 (c). However, the art does not teach that these reagents are kept in a kit with written instructions.

Zuk et al. teach that reagents for an immunoassay can be provided as kits as a matter of convenience and to optimize the sensitivity of the assay in the range of interest (col 22, line 62 - col 23, line 4). The instructions of the kit were also known as taught by WO 99/56755. Moreover, instructions are printed matter which have been long been held to distinguish a claimed structure over the prior art only where the printed matter functions in cooperation with the structure. Here there is no such functional cooperation between the printed instructions and the kit's structural components. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include the necessary reagents to perform the immunodiagnostic assay in a kit format for the convenience and economy of the user. One would have been motivated to assemble the reagents in a kit format to

standardize the reagents for the optimization the assay for use in a clinical diagnostic laboratory or physician's office.

Conclusion

14. No claims are allowed.

15. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 156, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571) 272-0956.

Respectfully,

/Padma V Baskar/

Examiner, Art Unit 1645

/Robert B Mondesi/

Supervisory Patent Examiner, Art Unit 1645